

TRANSMITTAL LETTER

(General - Patent Pending)

Docket No.

112703-211

In Re Application Of: Roman Barabolak, et al.

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Serial No.
10/035,320Filing Date
November 8, 2001Examiner
S. RoseGroup Art Unit
1614

Title: "ANTI-PLAQUE EMULSIONS AND PRODUCTS CONTAINING SAME"

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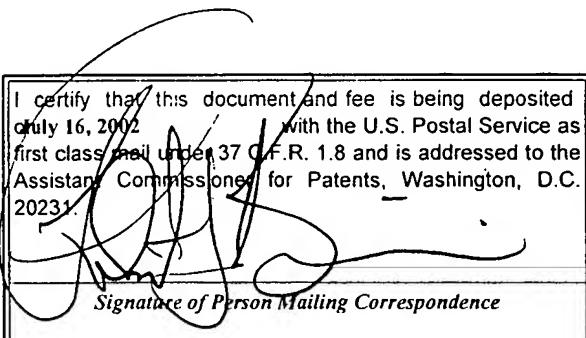


Dated: July 16, 2002

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Barabolak et al.

Appl. No.: 10/035,320

Filed: November 8, 2001

Title: "ANTI-PLAQUE EMULSIONS AND PRODUCTS CONTAINING
SAME"

Art Unit: 1614

Examiner: S. Rose

Docket No.: 112703-211

Commissioner for Patents
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RESPONSE TO OFFICE ACTION

SIR:

Please enter the following Response in the above-identified patent application.

REMARKS

This Response is submitted in response to the Office Action mailed on April 17, 2002.

In the Office Action, Claims 1-22 are provisionally rejected as being unpatentable based on obviousness-type double patenting. Claims 1, 2, 4, 5, 15, 19, and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,236,699 ("Libin I") (See, Office Action, p. 5). Claims 1-7, 9-11, 13, 15-17, and 19-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,487,902 ("Andersen") (See, Office Action, p. 7). Claims 1, 2, 5-7, 9, 13-16 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,380,530 ("Hill"), in view of Libin I. (See, Office Action, p. 8). Claims 1-5, 15 and 19-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Libin I (See, Office Action, p.18). Claims 6, 7, 9-12, 16-

18, and 22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Libin I* in view of *Hill*. (See, Office Action, p. 20). Claims 13 and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Libin I* and *Hill* in view of U.S. Patent No. 5,711,961 (“*Reiner*”) and U.S. Patent No. 5,248,508 (“*Reed*”)(See, Office Action, p. 20). Claim 24 is rejected under 35 U.S.C. § 103(a) as being unpatentable in view of either U.S. Patent No. 5,855,872 (“*Libin II*”) or U.S. Patent No. 5,945,089 (“*Libin III*”)(See, Office Action, p. 22).

In the Office Action, Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 25-32 of co-pending application No. 09/453,383. In response, Applicants submit that, upon issuance of either one of the co-pending applications, a Terminal Disclaimer will be filed to address this rejection.

In the Office Action, Claims 1, 2, 4, 5, 15, 19 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Libin I*.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1981) (emphasis added). Yet, the Patent Office relies on the Merck Index to support this anticipation rejection. Indeed, the Patent Office’s reliance on the Merck Index is a tacit admission that *Libin I* fails to anticipate Claims 1, 2, 4, 5, 15, 19 and 23.

Moreover, *Libin I* fails to disclose each and every feature as required by independent Claims 1 and 15. Independent Claim 1 requires an anti-plaque emulsion that includes an emulsifier, triclosan, and a surfactant. Independent Claim 15 requires a

method for reducing plaque that includes the step of orally applying to the mouth an emulsion which includes an emulsifier, triclosan, and a surfactant. The remaining rejected claims depend from either Claims 1 or 15 and therefore, as a matter of law, incorporate each of the features of either one of these claims.

In contrast, *Libin I* fails to disclose the emulsion features of independent Claims 1 and 15. Nowhere does *Libin I* disclose an emulsion and use in relation to its anti-plaque mouth rinse. Applicants question how the Patent Office can rely on *Libin I* where *Libin I* discloses a solubilizer that is utilized in a sufficient amount to solublize triclosan. *See, Libin I*, Claim 1, col. 1 at lines 53-60. In this regard, *Libin I* emphasizes solubilizing, not emulsifying triclosan.

Based on the above, the Patent Office's rejection of Claims 1, 2, 4, 5, 15 and 19 and 23 is improper. Applicants submit that *Libin I* fails to anticipate these claims. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, Claims 1-7, 9-11, 13, 15-17 and 19-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Andersen*. The Patent Office essentially asserts that *Andersen* discloses each and every feature of the rejected claims.

Applicants submit that the Patent Office incorrectly relies on *Andersen* as an anticipatory reference. Independent Claims 1 and 15 each include an emulsion feature, as previously discussed. Independent Claim 6 features a gum that includes an emulsifier, triclosan, and a surfactant. The remaining rejected claims depend from independent Claims 1, 6 and 15 and therefore, as a matter of law, incorporate each of the features of these independent claims.

In contrast, *Andersen*, like *Libin I*, requires a solublizing agent to solublize the active agent, such as triclosan, in order to control the release of said active agent. *See, Andersen*, Claim 1, col. 10 at line 57-61. Further, *Andersen* clearly makes a distinction between the use of an emulsifier as compared to solublizers. *Andersen* states that the solublizing effect of an emulsifier “is usually of a small extent” as compared to the effect of the solublizers. *See, Andersen*, col. 7, lines 18-26. This distinction is important as *Andersen* further recognizes that the accelerated, controlled release of the active agents is obtained by adding at least one solublizer. *See, Andersen*, Abstract. In this regard, *Andersen*, like *Libin I*, effectively emphasizes the use of solublizers rather than the emulsion and emulsifier features of the claimed invention.

Based on the fact that *Andersen* fails to disclose each and every feature of the rejected claims, Applicants submit that *Andersen* fails to anticipate Claims 1-7, 9-11, 13, 15-17 and 19-21. Accordingly, Applicants respectfully request that the rejection of these claims under 35 U.S.C. § 102(b) be withdrawn.

In the Office Action, Claims 1, 2, 5-7, 9, 13-16 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hill*. The Patent Office relies on *Libin I* to remedy the deficiencies of *Hill*. Applicants submit that this rejection is improper.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so, either in the references themselves or in the knowledge generally available to one ordinarily skilled in the art. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). The mere fact that the references can normally be combined or modified does not render

the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

The Patent Office admits that *Hill* fails to teach or suggest the combination of an emulsifier and a surfactant as required by the rejected claims. Further, *Libin I* cannot be used to remedy the deficiencies of *Hill*. The Patent Office incorrectly relies on *Libin I* as providing a motivation or suggestion to replace the single surfactant or single emulsifier of *Hill* with the combination thereof. Moreover, *Hill* provides no such motivation to combine *Hill* and *Libin I*.

Even if combinable, *Libin I* fails to provide such teaching or suggestion as previously discussed. Nowhere does *Libin I* discuss emulsifiers, let alone the combination of emulsifiers and surfactants. The clear emphasis of *Libin I* is to solubilize agents, such as triclosan, in order to enhance anti-bacterial activity. *See, Libin I*, col. 3, lines 53-60. Therefore, *Hill* and *Libin I*, alone or in combination, fail to teach or suggest each and every feature of the rejected claims.

Based on the fact that *Hill* and *Libin I*, alone or in combination, fail to teach or suggest every feature of the rejected claims, Applicants submit that *Hill* and *Libin I* fail to render obvious Claims 1, 2, 5-7, 9, 13-16 and 19. Accordingly, Applicants respectfully request that the rejection of Claims 1, 2, 5-7, 9 13-16 and 19 under 35 U.S.C. § 103(a) be withdrawn.

The Patent Office rejects Claims 1-5, 15, 19 and 20-21 under 35 U.S.C. § 102(b) as being anticipated by *Libin I*. From the outset, Applicants question why the Patent Office raises this anticipation rejection of Claims 1-5, 15, 19 and 20-21 based on *Libin I* (See Office Action, p. 18) when the Patent Office already raised an anticipation rejection

of Claims 1, 2, 4, 5, 15, 19, and 23 based on *Libin I* (See Office Action, p. 5).

Nevertheless, Applicants will address this seemingly redundant rejection.

Despite the fact that “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference,” *Verdegaal Bros., supra*, the Patent Office relies on the Merck Index (in addition to *Libin I*) to support its anticipation rejection. Indeed, the Patent Office’s reliance on the Merck Index is again a tacit admission that *Libin I* fails to anticipate Claims 1-5, 15, 19 and 20-21.

In addition to improperly relying on the Merck Index as secondary source to support its anticipation rejection, the Patent Office additionally appears to overcome the emulsifier element deficiency by relying on the *Hill* and/or *Anderson* references. The Patent Office does so despite the fact that the relevant rejection as noted on page 18 of the Office Action is based on anticipation rather than obviousness. Applicants thus question how the Patent Office can properly rely on any secondary reference such as the Merck Index, *Hill* and *Anderson* to remedy the deficiencies of *Libin I* when the rejection is based on 35 U.S.C. § 102.

In any case, the argument of the Patent Office appears to be that the *Hill* and/or *Anderson* references disclose that nonionic surfactants were well known in the art as emulsifiers and that such teachings would have been inherent within the disclosure of *Libin I* to anticipate Claims 1-5, 15, 19 and 20-21. Applicants respectfully submit that *Libin I* does not teach the claimed invention.

In this regard, *Libin I* does not disclose an emulsifier, a fact that is even admitted by the Patent Office on page 18 of the Office Action. *Libin I* fails to disclose the

emulsion features of independent Claims 1 and 15. Nowhere does *Libin I* disclose an emulsion and use in relation to its anti-plaque mouth rinse. Applicants question how the Patent Office can rely on *Libin I* where *Libin I* discloses a solubilizer that is utilized in a sufficient amount to solublize triclosan. *See, Libin I*, Claim 1, col. 1 at lines 53-60. In this regard, *Libin I* effectively teaches away from the emulsion features of independent Claims 1 and 15. *Libin I* emphasizes solubilizing not emulsifying triclosan.

Moreover, *Hill* and *Anderson* do not bolster the *Libin I* disclosure in this regard. Neither *Hill* nor *Anderson* disclose the use of a nonionic surfactant as an emulsifier.

Hill specifically sets forth within Col. 10, lines 1-7 that the disclosed chewing gum is coated with an emulsion containing a surfactant or an emulsifier rather than one component acting as both. *Anderson* merely discloses solubilizers which may be used to solublize a resin within a chewing gum base. Clearly, the *Hill* and *Anderson* references do not teach the use of a nonionic surfactant as an emulsifier.

Additionally, *Libin I* does not set forth the same component concentration ranges found within at least some of Claims 1-5, 15, 19 and 20-21. Specifically, Claims 3 and 20 provide that triclosan comprises approximately 3% to about 30% by weight of the claimed emulsion while the surfactant, namely cetylpyridinium chloride, comprises approximately 0.1% to about 10% by weight of that same emulsion as set forth within Claims 4 and 21.

Libin I, however, sets forth in Col. 3, lines 49-52 that triclosan typically comprises about 0.01% to 0.05% by weight of the disclosed mouth rinse composition and in Col. 4, lines 1-5 that the cetylpyridinium chloride component comprises typically about 0.020% to about 0.03%, preferably about 0.025% by weight of the mouth rinse

composition. *Libin I* does not teach the concentration ranges set forth within Applicants' claims as asserted by the Patent Office.

As a result, *Libin I* does not anticipate Claims 1-5, 15, and 19-21 because the reference does not teach an emulsifier and does not set forth the same concentration ranges required by some of those claims.

Accordingly, Applicants respectfully request the 35 U.S.C. § 102(b) rejection of Claims 1-5, 15, and 19-21 be withdrawn.

Claims 6-7, 9-12, 16-18 and 22 stand rejected as being obvious over *Libin I* in view of *Hill*. Applicants respectfully submit that the rejection is improper.

The Patent Office asserts that *Libin I* motivates the selection of triclosan and cetylpyridinium chloride as suitable components within the emulsion coatings of *Hill* because *Libin I* discloses that such components have anti-plaque benefits.

Applicants respectfully assert that merely because *Libin I* teaches a combination of triclosan and cetylpyridinium to achieve anti-plaque benefits does not teach or suggest to one of ordinary skill in the art the desirability of their inclusion within the emulsions taught by *Hill*. Furthermore, as reiterated above, *Libin I*, alone or in combination with *Hill*, does not teach or suggest the use of a nonionic surfactant as an emulsifier to arrive at Applicants' claimed invention.

Indeed, *Hill* discloses a variety of surfactants, but not that such surfactants can also function as emulsifiers. Thus, combining the teachings of *Libin I* with that of *Hill* would fail to arrive at Applicants' claimed invention because the required emulsifier element would be missing.

Accordingly, Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claims 6-7, 9-12, 16-18 and 22 be withdrawn.

The Patent Office has additionally rejected Claims 13 and 14 under 35 U.S.C. § 103(a) as being obvious over *Libin I* in view of *Hill*, and in further view of *Reiner* and *Reed*. Applicants respectfully submit that the rejection is improper.

The Patent Office asserts that *Libin I*, in combination with *Hill* and in further combination with any of the other chewing gum references (*Reiner* and *Reed*), teaches the chewing gum compositions set forth within Claims 13 and 14.

Applicants respectfully assert that the *Hill* reference does not teach or suggest the use of a nonionic surfactant as an emulsifier to modify the disclosure of *Libin I* to arrive at Applicants' claimed invention. Thus, *Hill* does not teach or suggest the desirability of combining its teachings with those of *Libin I*.

Moreover, there is no motivation to combine the various teachings of any of the secondary references with those of *Libin I* to arrive at Applicants' claimed invention. Such references do not provide any teaching or suggestion of an anti-plaque emulsion which contains an emulsifier, triclosan, and a surfactant like that of the claimed invention.

Additionally, the Patent Office also fails to indicate with any particularity within the instant Office Action, the desirability within any of the cited references to combine their respective teachings with those of *Libin I*.

Therefore, *Libin I*, alone or in combination with *Hill*, and in further combination with *Reiner* and *Reed*, does not render obvious the chewing gum compositions set forth within Claims 13 and 14. The asserted combination of references by the Patent Office

does not teach or suggest an anti-plaque emulsion containing an emulsifier, triclosan, a surfactant which may be incorporated within a chewing gum composition like that of the claimed invention.

Accordingly, Applicants respectfully request the 35 U.S.C. § 103(a) rejection of Claims 13 and 14 be withdrawn.

The Patent Office has additionally rejected Claim 24 under 35 U.S.C. § 103(a) as being obvious over *Libin I* in view of either *Libin II* or *Libin III*. Applicants respectfully submit that the rejection is improper.

The Patent Office asserts that *Libin I* in combination with *Libin II* and *Libin III* teaches the method set forth within Claim 24. More specifically, the Patent Office argues that it would have been obvious to one skilled in the art to combine the semi-solid anti-plaque compositions of *Libin II* and *Libin III* with the mouthwash of *Libin I* to arrive at the claimed invention.

Claim 24 depends from independent Claim 15 and therefore, as a matter of law, incorporates all of the features and limitations found in Claim 15. Claim 15 is directed toward a method of reducing plaque by applying to the mouth an emulsion comprising an emulsifier, triclosan, and a surfactant. As noted previously, however, *Libin I* does not disclose an emulsifier, a fact that is even admitted by the Patent Office on page 18 of the Office Action. Thus, *Libin I* fails to disclose the emulsion features of independent Claim 15. Moreover, nowhere does *Libin I* disclose an emulsion and use in relation to its anti-plaque mouth treatment. Therefore, even if combinable, the combined teachings of the cited references do not disclose the claimed invention as set forth in Claim 24.

Additionally, there is no motivation to combine the various teachings of *Libin II* and *Libin III* with those of *Libin I* to arrive at Applicants' claimed invention. In this regard, the preparations disclosed in *Libin II* and *Libin III* are designed to treat infections involving herpes simplex virus and mucositus, respectively. *Libin II* and *Libin III* do not provide any teaching or suggestion of the utility of combining a gel composition with an anti-plaque emulsion for the purpose of reducing plaque in the mouth as required by Claim 24. Similarly, *Libin I* provides no motivation to combine *Libin I*, *Libin II*, and *Libin III*.

Accordingly, Applicants respectfully request the 35 U.S.C. § 103(a) rejection of Claim 24 be withdrawn.

Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,



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